

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

CAROL LEWIS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.:
	)	1:15-CV-13530-NMG
	)	
DON WRIGHT,	)	
Acting Secretary of Health	)	
and Human Services, <sup>1</sup>	)	
	)	
Defendant.	)	
_____	)	

**DEFENDANT’S REPLY**  
**TO PLAINTIFF’S MOTION TO ALTER OR AMEND JUDGMENT**

Defendant, Secretary of the Department of Health and Human Services (HHS), requests that Plaintiff’s Motion to Alter or Amend Judgment be denied. As set forth below, Plaintiff fails to point to any “manifest error of law or newly discovered evidence” that would affect the outcome of the Judgment. Moreover, her argument on mootness is untimely.

**I. THE APPLICABLE STANDARDS  
FOR PLAINTIFF’S POST-JUDGMENT MOTIONS.**

Plaintiff brings her Motion to Alter or Amend Judgment pursuant to Federal Rules of Civil Procedure, Rules 52 and 59. Rule 52(b) provides for the amendment of findings and conclusions issued by the Court; Rule 59(e) authorizes a motion to alter or amend a judgment. These motions “are closely related, and the same standard is generally applied.” *Ford v. Bender*, 2012 WL 1378651, at 1 (D. Mass.). With respect to these Rules, the First Circuit has held:

[t]he granting of a motion for reconsideration is an extraordinary remedy which should be used sparingly . . . . Unless the court has

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<sup>1</sup> Pursuant to Rule 25(d), Federal Rules of Civil Procedure, Don Wright, has been substituted for Thomas E. Price, M.D., in his official capacity as Acting Secretary of Health and Human Services.

misapprehended some material fact or point of law, such a motion is normally not a promising vehicle for revisiting a party's case and rearguing theories previously advanced and rejected.

*Palmer v. Champion Mortgage.*, 465 F.3d 24, 30 (1st Cir. 2006). The First Circuit has held that post-judgment relief is warranted only “when the original judgment evidenced a manifest error of law, if there is newly discovered evidence, or in certain other narrow situations.” *Biltcliffe v. CitiMortgage, Inc.*, 772 F.3d 925, 930 (1st Cir. 2014) (citing *Global Naps, Inc. v. Verizon New England, Inc.*, 489 F.3d 13, 25 (1st Cir. 2007)). “Parties should not use [such motions] to raise arguments which could, and should, have been made before the judgment issued.” *Estate of Rivera v. Doctor Susoni Hosp., Inc.*, 323 F. Supp. 2d 262, 265 (D. Mass. 2004).

The “Courts are entitled to expect represented parties to incorporate all relevant arguments in the papers that directly address a pending motion,” and late-filed arguments are untimely for consideration. *Boston Redevelopment Authority v. National Park Service*, 838 F.3d 42, 47 n. 4 (1<sup>st</sup> Cir. 2016), *quoting McCoy v. Mass. Inst. Of Tech.*, 950 F.2d 13, 22 n.7 (1<sup>st</sup> Cir. 1991) (court denied consideration of arguments first raised by plaintiff after the hearing on summary judgment motion). Motions under Rule 59(e) are “aimed at reconsideration, not initial consideration.” *FDIC Corp. v. World University, Inc.*, 978 F.2d 10, 16 (1st Cir.1992). Parties may not use them to “raise arguments which could, and should, have been made before the judgment issued.” *Id.* (*quoting FDIC Corp. v. Meyer*, 781 F.2d 1260, 1268 (7th Cir.1986)).

## **II. PLAINTIFF CANNOT PREVAIL ON HER MOOTNESS ARGUMENT**

### **A. Plaintiff's Argument that this Action is not Moot is Untimely.**

Plaintiff takes the position that the Court's decision is erroneous because her action is not moot. Based on Plaintiff's admission in her Opposition to HHS' Motion to Affirm HHS's Decision (Docket No. 53 at 10 n. 12), that she does not use the Medtronic Continuous Glucose

Monitor (CGM) that is at issue in this action, HHS filed its Reply brief arguing that the action was moot (Docket No. 57). Plaintiff filed no pleadings thereafter; she filed no response to Defendant's mootness argument. Plaintiff's argument "could, and should, have been made before the judgment issued;" *FDIC Corp. v. World University, Inc.*, 781 F.2d at 1268; and she did not do so. Accordingly, because Plaintiff's argument is untimely, it should not be considered by the Court.

**B. Plaintiff's Argument Fails to Show that the Court's Determination Of Mootness is a Manifest Error of Law.**

The Court properly found that Plaintiff's action is moot because Plaintiff, by her own admission, no longer uses the Medtronic CGM device for which her Complaint requests Medicare coverage. The Court correctly determined that, under these circumstances, Plaintiff "lacks a legal interest in the outcome of the case." Order at 4.

"The doctrine of mootness enforces the mandate that an actual controversy must be extant at all stages of the review, not merely at the time the complaint is filed." *Am. Civil Liberties Union of Mass. v. U.S. Conference of Catholic Bishops*, 705 F.3d 44, 52 (1st Cir. 2013). An action is moot "when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome[.]" and where "events have transpired to render a court opinion merely advisory[.]" *Id.* (citing *D.H.L. Assocs., Inc. v. O'Gorman*, 199 F.3d 50, 54 (1st Cir. 1999); *Mangual v. Rotger-Sabat*, 317 F.3d 45, 60 (1st Cir. 2003); *Libertarian Party of N.H. v. Gardner*, 638 F.3d 6, 12 (1st Cir. 2011)).

As set forth in her Complaint and in her Motion here, Plaintiff's requests for relief are requests for injunctive and declaratory relief.<sup>2</sup> Plaintiff requests as relief:

1. An order setting aside the Secretary's decision that CGM is not covered;

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<sup>2</sup> See *infra* note 3.

2. An order declaring CGM is eligible for Medicare coverage;
3. An order remanding this action to the Secretary with instruction to cover Ms. Lewis's CGM and related supplies;
4. An order that this Court will retain jurisdiction over the decisions at issue until the Secretary's payment of the claims at issue has been completed; [and]
5. A declaratory judgment that the Secretary's delay in adjudicating Medicare appeals violates Federal law.

Complaint at 20. Plaintiff's request for an order setting aside the Secretary's decision is a request for injunctive relief. *See Cape Cod Commercial Hook Fishermen's Ass'n v. Daley*, 30 F. Supp. 2d 111, at n. 11 (D. Mass. 1998) ("[R]equest for a court order setting aside an administrative body's decision "would, of course, be injunctive in nature"). Plaintiff's requests for orders declaring CGMs eligible for Medicare coverage, remanding the action with instruction to cover CGMs, retaining jurisdiction, and declaring that the Secretary has violated federal law are requests for declaratory relief. *See generally* 28 U.S.C. § 2201(a) (defining a declaratory judgment as one which "declare[s] the rights and other legal relations of any interested party seeking such declaration[.]").

A party's request for injunctive or declaratory relief is moot if "a court cannot provide meaningful relief to the allegedly aggrieved party." *Am. Civil Liberties Union of Mass.*, 705 F.3d at 52. Even when an action "poses a live controversy when filed, the mootness doctrine requires a federal court to refrain from deciding it if events have so transpired that the decision will neither presently affect the parties' rights nor have a more-than-speculative chance of affecting them in the future." *Columbian Rope Co. v. West*, 142 F.3d 1313, 1316 (D.C. Cir. 1998). In considering requests for declaratory or injunctive relief, the First Circuit has emphasized that "to withstand a mootness challenge, the facts alleged must show that there is a substantial controversy . . . of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Am. Civil Liberties Union of Mass.*, 705 F.3d at 54 (emphasis in original) (quoting *Preiser v. Newkirk*, 422 U.S. 395, 402 (1975)).

Plaintiff has failed to show that there is either “a substantial controversy” or “sufficient immediacy” to warrant the issuance of the injunctive and declaratory relief that she requests. The Complaint requests that the Court order HHS to extend Medicare reimbursement to the Medtronic CGM. Plaintiff now uses a Dexcom G5 CGM, which is covered by Medicare and no longer uses the Medtronic CGM. The Dexcom CGM, unlike the Medtronic CGM, permits Plaintiff to monitor her diabetes without having to confirm the CGM’s reading by using another monitoring method, a fingerstick blood glucose test, prior to adjusting treatment.<sup>3</sup> Because Plaintiff no longer uses the Medtronic CGM – and, instead, uses the Dexcom CGM, which is covered by Medicare -- Plaintiff has no legally cognizable interest in requesting Medicare coverage for the Medtronic CGM and no cognizable interest in the outcome of her action. A decision by this Court on HHS’ coverage of her Medtronic CGM “will neither presently affect the parties’ rights nor have a more-than-speculative chance of affecting them in the future.”<sup>4</sup> *Columbian Rope Co.*, 142 F.3d at 1316 (An unsuccessful bidder on a government contract that had been fully performed no longer had a legal stake in the outcome of the case and any speculative interest the bidder might have in future contracts was insufficient to create a live controversy). *See* HHS’ Reply Brief (Docket No. 57) at 1-3. Moreover, Plaintiff makes no

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<sup>3</sup> *Dexcom G5 Mobile Continuous Glucose Monitoring System – P120005/S041*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm533969.htm> (Dec. 21, 2016) (approving Dexcom G5 as a device “designed to replace fingerstick blood glucose testing for diabetes treatment decisions.”) *Id.* CMS Ruling No. 1682 recognizes the Dexcom G5 CGM as durable medical equipment (DME) for purposes of approved Medicare coverage.

<sup>4</sup> Plaintiff argues that patients may need to switch back and forth between different CGM devices, some which meet the requirements of CMS Ruling No. 1682, and some which do not. Pl’s M at note 10. Plaintiff has failed to introduce, and the administrative record fails to contain, any medical evidence supporting her claim; Plaintiff has also failed to indicate that she will switch back to the Medtronic CGM. Therefore, any assertion by Plaintiff that she may do so in the future is entirely speculative.

argument – nor could she -- that Medicare coverage of her *prior* device would affect her rights at this time or in the future.

Plaintiff now argues – as noted, for the first time -- that the Court should interpret the Complaint as requesting compensatory damages in the form of payment for her past claims. *See* Pl.’s Mot. at 9. However, Plaintiff did not, in fact, seek this relief in her Complaint.<sup>5</sup>

Plaintiff also argues that this Court should apply the “voluntary cessation doctrine”. The voluntary cessation doctrine “traces to the principle that a party should not be able to evade judicial review, or to defeat a judgment, by temporarily altering questionable behavior.” *City News & Novelty, Inc. v. City of Waukesha*, 531 U.S. 278 (2001). Plaintiff states that a ruling on coverage for the Medtronic CGM is necessary so that HHS will not continue to deny coverage “for the Medtronic devices . . .,” and demonstrates “that CMS Ruling 1682 [granting Medicare coverage for the Dexcom CGM] even applie[s] to her claims, or that it would not be withdrawn.” Pl.’s Mot. 10. Is she taking the position that the Court should rule on her past use of the Medtronic CGM just in case Medicare denies coverage for the Dexcom CGM sometime in the future? This would not be a present case or controversy; and it could not fall within the “voluntary cessation doctrine”, because Medicare coverage of the Dexcom is not being challenged in this action and has no bearing on her request for Medicare coverage for a Medtronic CGM. And, of course, Plaintiff presents no evidence or even a bare assertion that

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<sup>5</sup> The Complaint requests an order awarding legal fees and costs of suit incurred by Plaintiff. However, the Supreme Court has made clear that an interest in attorney’s fees is “insufficient to create an Article III case or controversy where none exists on the merits of the underlying claim.” *Lewis v. Cont’l Bank Corp.*, 494 U.S. 472, 480 (1990). Likewise, the complaint requests “[s]uch other relief as this Court may deem and consider appropriate.” This language cannot create a claim or controversy when the case is otherwise moot. *See Flittie v. Erickson*, 724 F.2d 80, 82 (8th Cir. 1983).

HHS plans to withdraw its approval of the Dexcom CGM.<sup>6</sup> Medicare Ruling 1682 is unambiguous; it grants coverage for “therapeutic” CGMs, such as the Dexcom, that have received approval from the FDA for use in place of a fingerstick blood glucose test, and Plaintiff’s past Medtronic CGM may not be used in place of the fingerstick test. See HHS’ Memorandum of Law in Support of Motion to Affirm at 6-8.<sup>7</sup>

Plaintiff also asserts, as what she terms a voluntary cessation argument, that the Court should reconsider its Order because the Secretary may continue to deny her requests for coverage for any CGM. To the extent that Plaintiff is attempting to argue that her case is capable of repetition, yet evading judicial review, the Secretary notes that the capable of repetition, yet evading judicial review exception applies “only in exceptional situations, where a plaintiff can show that (1) the challenged action was in its duration too short to be fully litigated prior to its cessation or expiration, and (2) there was a reasonable expectation that the same complaining party would be subjected to the same action again.” *Am. Civil Liberties Union of Mass.*, 705 F.3d at 57 (citations omitted). Plaintiff bears the burden and “must show a reasonable expectation or demonstrated probability . . . that it will again be subjected to the alleged illegality.” *Id.* In this case Plaintiff has failed to demonstrate that she will “again be subjected to the alleged illegality” because, as noted, Plaintiff now uses the Medicare-eligible Dexcom (Plaintiff does not even assert that she will use her Medtronic CGM again.).<sup>8</sup> There is no basis

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<sup>6</sup> In addition, “[t]he voluntary cessation doctrine does not apply when the voluntary cessation of the challenged activity occurs because of reasons unrelated to the litigation.” *Am. Civ. Liberties Union of Mass.*, 705 F.3d at 55

<sup>7</sup> As noted in CMS Ruling No. 1682, the Secretary revised his stance on the coverage of CGMs due to technological advances and not due to any concerns related to Plaintiff’s case. Plaintiff argues that prior inconsistent administrative rulings on Medicare coverage of her Medtronic CGM make it possible that the Secretary may deny coverage for her Dexcom G5 CGM. However, Plaintiff has failed to point to any instances in which the Secretary has acted contrary to CMS Ruling 1682.

for Plaintiff's argument that she is entitled to an exception to the mootness doctrine because of the voluntary cessation and capable of repetition yet evading review arguments.

### **III. PLAINTIFF CANNOT PREVAIL ON HER ARGUMENT THAT SHE LACKED NOTICE THAT THE COURT COULD DISMISS HER COMPLAINT.**

Plaintiff takes the position that the Judgment should be altered or amended because she did not have notice that the Court planned to convert HHS' Motion to Affirm to a motion for summary judgment and dismiss her Complaint. Ab initio, the Court did not convert HHS' Motion to Affirm to a motion for summary judgment. The Court ruling denied as moot HHS' Motion to Affirm – as it denied Plaintiff's Motion for Summary Judgment. Whichever formal course the Court's dismissal took, it is insignificant. It has long been recognized that “the summary judgment rubric has a ‘special twist in the administrative law context.’” *Boston Redevelopment Authority v. Nat'l Park Service*, 838 F. 3d at 47, *quoting Assoc'd Fisheries of Maine, Inc. v. Daley*, 127 F.3d 104, 109 (1<sup>st</sup> Cir. 1997). In an action seeking review of an agency decision, a motion for summary judgment is “simply a vehicle to tee up a case for judicial review.” *Stephanie v. Blue Cross Blue Shield*, 852 F.3d 105, 110 (1<sup>st</sup> Cir. 2017). A review of an administrative decision is a review of whether an agency action is contrary to the substantial evidence in the administrative record, and it does not, in the context of administrative review, take the role of an ordinary summary judgment motion regarding disputes of fact, determinations de novo, etc. *Boston Redevelopment Auth.*, 838 F.3d at 47. The form of the parties' motions in the administrative review context “is not significant; substance must prevail over form.” *Stephanie*, 852 F.3d at 110.<sup>9</sup>

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<sup>9</sup> Plaintiff also takes the position that she lacked a reasonable opportunity to present all the material that is pertinent to the motions before the Court. Plaintiff's Mem.at 7. However, as noted, Plaintiff filed no response to HHS' Reply memorandum, and as the Court noted, did not request leave to file a reply to HHS' mootness argument. Order at 3, footnote 1.



**IV. EVEN IF NOT DISMISSED FOR MOOTNESS, THE COMPLAINT SHOULD BE DISMISSED FOR THE REASONS SET FORTH IN HHS' MEMORANDUM IN SUPPORT OF MOTION TO AFFIRM HHS' DECISION**

In the event that this Court considers reversing its decision to dismiss, HHS reasserts the arguments set forth in its Motion to Affirm HHS' Decision and its Reply brief. Briefly, judgment for HHS would be the appropriate outcome because HHS' final decision denying Medicare coverage for Plaintiff's Medtronic CGM is supported by substantial evidence. To be covered for reimbursement by Medicare, an item or service must fall within a defined benefit category, must be reasonable and necessary for the diagnosis or treatment of an injury, and must meet all applicable statutory and regulatory requirements. *See* 42 U.S.C. §§ 1395k, 1395x, 1395y(a)(1)(A), 68 Fed. Reg. at 55,635. The Medtronic CGM is not covered by Medicare because it does not fall within a defined benefit category, namely, the durable medical equipment (DME) benefit category. To be covered as DME, a device must primarily and customarily serve a medical purpose. Since the Medtronic CGM is merely a precautionary device -- because it is unreliable as a basis for making therapeutic adjustments -- it does not primarily and customarily serve a medical purpose and cannot qualify as DME. *See* Administrative Record ("A.R.") 10-11 (the manufacturer of the Medtronic CGM cautions that it must be used in conjunction with traditional finger stick testing), AR 888 (Plaintiff's physician directed that Plaintiff must consult home blood glucose monitor before adjusting pump doses); AR 11 (the FDA states that Plaintiff's CGM device "is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required").<sup>10</sup>

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<sup>10</sup> As noted, the Medtronic CGM is distinguishable from the Dexcom CGM that the Plaintiff currently uses because the Dexcom CGM permits Plaintiff to make direct therapeutic adjustments based solely on its readings and the Medtronic CGM does not. Because the Dexcom CGM primarily and customarily serves a medical purpose, it qualifies for Medicare coverage.

**V. CONCLUSION**

Because the Court's "judgment [does not] evidence[] a manifest error of law" *Biltcliffe*, 772 F.3d at 930, HHS requests that the Court deny Plaintiff's motion to alter or amend the judgment.

Respectfully submitted,

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Certificate of Service

I hereby certify that the foregoing will be filed through the electronic filing system of the Court, which system will serve counsel for Plaintiff electronically, on this second day of October 2017.

/s/ Anita Johnson